

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2553]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Citizen Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

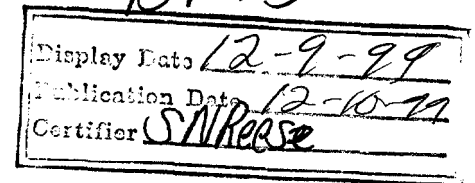
ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

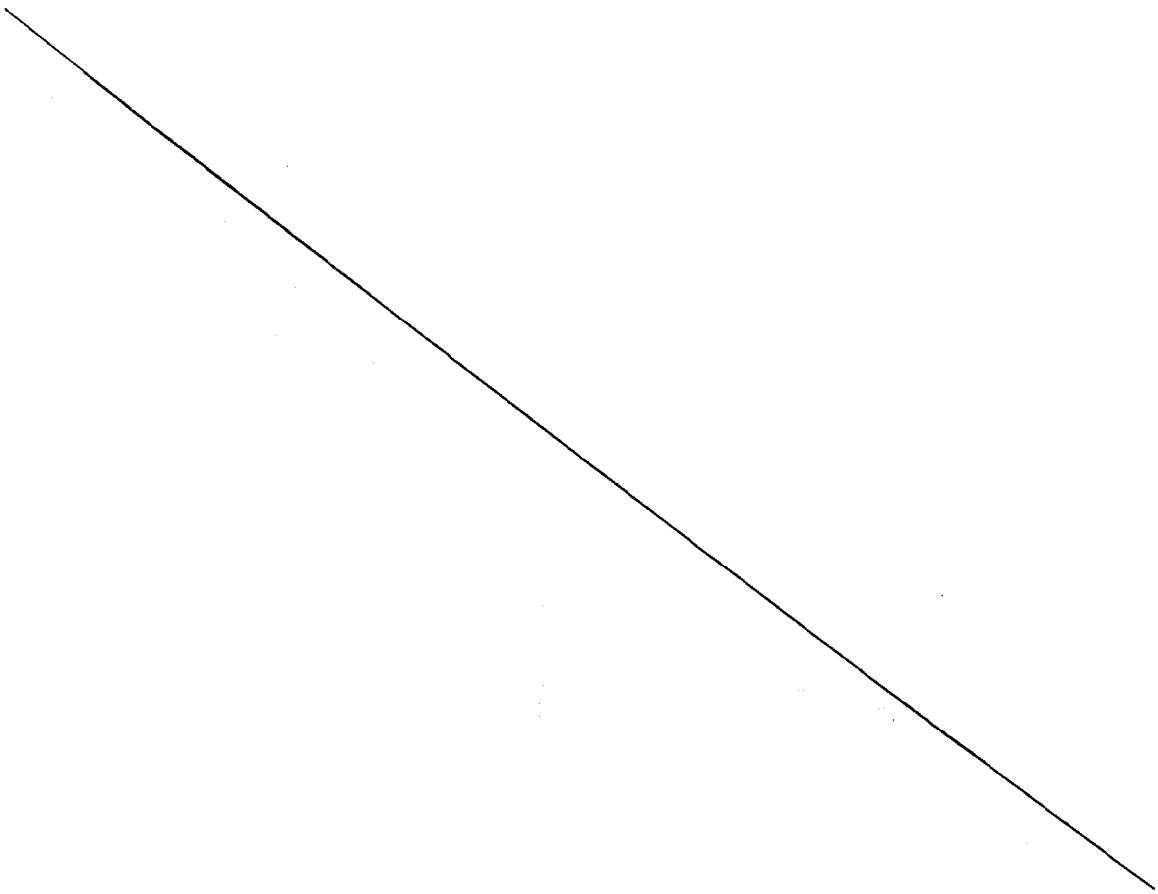
Citizen Petition-21 CFR 10.30 (OMB Control Number 0910-0183)—Extension

The Administrative Procedures Act (5 U.S.C. 553(e)) provides that every agency shall accord any interested person the right to petition for issuance, amendment, or repeal of a rule. Section



10.30 provides that any person may submit to the agency a citizen petition requesting the Commissioner of Food and Drugs to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. The information is used by the agency to determine the need or desirability of the requested action and also to determine if the submitted information is sufficient to support the action. FDA determines if the submitted information is sufficient to support the action. FDA determines whether or not to grant the petition based on the information submitted. The affected respondents are individuals or households, State or local governments, nonprofit institutions and businesses or other for-profit institutions or **groups**.

In the **Federal Register** of June 9, 1998 (63 **FR** 3 1502), the agency requested comments on the proposed collections of information. No significant comments were received.



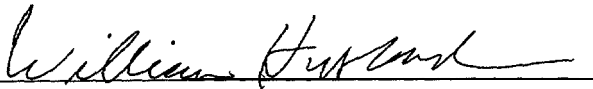
FDA estimates the burden of this collection of information as follows:

TABLE 1 .-ESTIMATED ANNUAL REPORTING BURDEN*

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	120	21	120	12	1,440

* There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 6, 1999



William K. Hubbard
Senior Associate Commissioner for Policy, Planning, and Legislation

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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